

REMARKS

This Application has been carefully reviewed in light of the Office Action mailed November 5, 2003. At the time of the Office Action, Claims 1, 3-11, 24 and 25 were pending in this Application. Claims 1, 3-11, 24 and 25 were rejected. To expedite allowance and further clarify the invention, Applicant has amended Claim 1 to better define various features of the invention. Claim 3 has been cancelled. Claims 27-41 have been added. No new matter is presented by these claims. Applicant respectfully requests reconsideration and favorable action in this case.

Rejection under 35 U.S.C. § 102

Claims 1, 5, 7-11, 24 and 25 stand rejected by Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,621,035 issued to Mark B. Lyles et al. (hereinafter "'035 Lyles"). Applicant respectfully traverses and submits that '035 Lyles does not include at least one element of the claims. To serve as the proper basis for any rejection under §102, a single reference must contain each and every element of the rejected claim. As admitted by the Examiner in the Office Action dated November 5, 2003, at page 4, lines 1-2 "Lyles does not each the exact porosity of the composition or the silicon dioxide content on the surface of the composition." Accordingly, it appears to Applicant that, by the Examiner's own reasoning, at least two elements of Claim 1 (and new Claim 27) are missing from the Lyles '035 reference. If Applicants have misunderstood the Examiner, clarification is respectfully requested.

Additionally, Applicants note that Lyles '035 lacks any reference to any metal oxide in addition to alumina, as recited in cancelled Claim 3 and presently amended Claim 1 as well as new dependent Claim 28. Specifically, while Lyles '035 does discuss the addition of various chemicals in preparing a silica material, no non-alumina oxides are added other than boron oxide. Boron is well understood in chemistry to be a semi-metal and not a metal. This may be verified through reference to most periodic tables.

Further, Applicants note that Lyles '035 lacks any reference to a silica gel, as recited in Claim 7 and new Claim 27. The Lyles '035 reference discusses only silica fibers which are then fused and provides not description of any silica gel in the composition disclosed therein.

Further, the Lyles '035 does not disclose the use of a silica gel to reinforce a composition, as claimed in Claims 38-39.

Accordingly, the Lyles '035 reference lacks at least one and most likely several elements of independent Claims 1 and 27 and, consequently, all dependent claims.

Claims 1, 3-5, 7-11, 24 and 25 stand rejected by Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,951,295 issued to Mark B. Lyles et al. (hereinafter "'295 Lyles"). Applicant respectfully traverses and submits '295 Lyles does not include at least one element of the claims. To serve as the proper basis for any rejection under §102, a single reference must contain each and every element of the rejected claim. As admitted by the Examiner in the Office Action dated November 5, 2003, at page 4, final two lines "Lyles does not each the exact porosity of the composition or the silicon dioxide content on the surface of the composition." Accordingly, it appears to Applicant that, by the Examiner's own reasoning, at least two elements of Claim 1 (and new Claim 27) are missing from the Lyles '295 reference. If Applicants have misunderstood the Examiner, clarification is respectfully requested.

Additionally, Applicants note that Lyles '295 lacks any reference to an additional metal oxide, as recited in cancelled Claim 3 and presently amended Claim 1 as well as new dependent Claim 28. Specifically, while Lyles '295 does discuss the addition of various chemicals in preparing a silica material, no non-alumina oxides are added other than boron oxide. Boron is well understood in chemistry to be a semi-metal and not a metal. This may be verified through reference to most periodic tables.

Further, Applicants note that Lyles '295 lacks any reference to a silica gel, as recited in Claim 7 and new Claim 27. The Lyles '295 reference discusses only silica fibers which are then fused and provides not description of any silica gel in the composition disclosed therein. Further, the Lyles '295 does not disclose the use of a silica gel to reinforce a composition, as claimed in Claims 38-39.

Accordingly, the Lyles '295 reference lacks at least one and most likely several elements of independent Claims 1 and 27 and, consequently, all dependent claims.

Rejection under 35 U.S.C. § 103

Claims 1, 5, 7-11, 24 and 25 were rejected by Examiner under 35 U.S.C. § 103(a) as being unpatentable over '035 Lyles. Applicants traverse and submit that '035 Lyles fails to teach or suggest the inclusion of at least one element of all claims. Specifically, as discussed above, Lyles '035 lacks any reference to any additional metal oxides, as recited in cancelled Claim 3 and presently amended Claim 1 as well as new dependent Claim 28.

While Lyles '035 does discuss the addition of various chemicals in preparing a silica material, no non-alumina oxides are added other than boron oxide. Boron is well understood in chemistry to be a semi-metal and not a metal. This may be verified through reference to most periodic tables. Because boron is a semi-metal, which are known to have a variety of properties different from metals, the disclosure of boron oxide does not in any way teach or suggest the addition of an additional metal oxide.

Additionally, as described above, Applicants note that Lyles '035 lacks any reference to a silica gel, as recited in Claim 7 and new Claim 27. The Lyles '035 reference discusses only silica fibers which are then fused and provides not description of any silica gel in the composition disclosed therein. Nor does the Lyles '035 reference teach or suggest the addition of any material such as a silica gel. It particularly also does not teach or suggest the addition of a silica gel to reinforce the composition, as is claimed in Claims 38-39.

Claims 1, 3-5, 7-11, 24 and 25 were rejected by Examiner under 35 U.S.C. § 103(a) as being unpatentable over '295 Lyles. Specifically, as discussed above, Lyles '295 lacks any reference to any additional metal oxides, as recited in cancelled Claim 3 and presently amended Claim 1 as well as new dependent Claim 28.

While Lyles '295 does discuss the addition of various chemicals in preparing a silica material, no non-alumina oxides are added other than boron oxide. Boron is well understood in chemistry to be a semi-metal and not a metal. This may be verified through reference to most periodic tables. Because boron is a semi-metal, which are known to have a variety of properties different from metals, the disclosure of boron oxide does not in any way teach or suggest the addition of an additional metal oxide.

Additionally, as described above, Applicants note that Lyles '295 lacks any reference to a silica gel, as recited in Claim 7 and new Claim 27. The Lyles '295 reference discusses

only silica fibers which are then fused and provides not description of any silica gel in the composition disclosed therein. Nor does the Lyles '295 reference teach or suggest the addition of any material such as a silica gel. It particularly also does not teach or suggest the addition of a silica gel to reinforce the composition, as is claimed in Claims 38-39.

Claim 6 stands rejected by Examiner under 35 U.S.C. § 103(a) as being unpatentable over '035 Lyles or '295 Lyles in view of U.S. Patent 6,063,395 issued to Tommi Markkula et al. (hereinafter "Markkula"). Applicant respectfully traverses and submits that there is no motivation to combine Markkula with either Lyles reference and that Markkula actually teaches away from combination with a composition such as that disclosed in the Lyles references. Specifically, as the Examiner has correctly noted, neither Lyles references teaches the incorporation of a drug. Markkula does teach a drug delivery device comprising silica, but the device in Markkula is specifically an elastomer. This elastomer is produced by adding trifluoropropyl groups to the Si-atoms of siloxane units. (Markkula, Col. 2, Lines 60-64.) According to Markkula, this provides an advantage over other silicon-containing materials that are not flexible and smooth. (Markkula, Col. 1, Lines 62-65, and Col. 2, Lines 35-37.) In general, silicon-based elastomers contain an organic substituent on the Si-atom in the final product. The silica materials described in Lyles et al. are not elastomeric because they lack a carbon substituent on the Si-atom. Therefore the materials described in Lyles et al. fall within the group of materials Markkula considers to be inappropriate for use in drug delivery. Accordingly, there is no motivation provided in either of the Lyles references or the Markkula reference to combine any of these references.

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PATENT APPLICATION
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CONCLUSION

Applicant appreciates the Examiner's careful review of the application. Applicant has made an earnest attempt to place this case in condition for allowance. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests reconsideration and full allowance of the claims, as amended.

Applicant encloses a check in the amount of \$475.00 to cover the 3 Month Petition for Extension of Time fee. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 02-0383 of Baker Botts L.L.P.

If there are any matters concerning this application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.322.2580.

Respectfully submitted,

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